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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,054

09/26/2003

Laurie Engel

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07/28/2006

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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/673,054	Applicant(s) ENGEL ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-12, 16-29, 67-77, 79 and 122-124 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 13-15 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 125 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-12, 16-28, 67-77, 79 and 122-124 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/26/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/3/04, 3/29/04, 6/30/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 11, 2006 has been entered. Applicant's response filed January 25, 2006. Claims 30-66 and 80-121 have been cancelled. Claim 125 has been added.
2. Claims 4-5 and 13-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected species of invention. This application contains claim 4-5 and 13-15 drawn to an invention nonelected with traverse filed November 5, 2004. A complete reply to this office action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.
3. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objection/Rejection Maintained

4. The objection of claim 29 is maintained for the reasons set forth on page 6, paragraph 9 of the previous Office Action.

The objection was on the grounds that claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant did not respond to this objection and therefore it is maintained.

5. The rejection under 35 U.S.C. 103(a) paragraph is maintained for claims 1-3, 6-12, 16-28, 67-77, 79 and 122-124 for the reasons set forth on pages 3-7, paragraph 5 of the Final Office Action.

The rejection was on the grounds that Chu et al teach compositions comprising aqueous solutions of alkylglycoside or alkylthioglycoside, particularly (octylthiogluconate) (columns 1-2). Chu et al teach that the octylthiogluconate used in the compositions range from about 0.5 to about 5% w/v (column 2-3). Chu et al teach that the octylthiogluconate can be included in an aqueous solution at about 0.5% (v/w) to about 5% (v/w) (column 3). This meets the claims limitations "...at least 0.4% and less than 1% (w/v)" and "...between 0.4% and 0.6% (w/v)". Chu et al teach that buffers such as TRIS or HEPES can be added to the compositions to maintain a physiological pH of about 7-8 (column 2). Chu et al teach that the buffers can be maintained at a pH of 7.5 (column 3, Example II). Chu et al teach that lysozyme (reduces non-specific binding) can be added to the compositions (column 24, Example 4). Chu et al teach that the invention was used to prepare, extract, detect, purify and collect the isolated proteins (see Examples I-V, columns 3-6). Chu et al teach that the protein products are incubated on Nickel charged resins (magnetic) and further purified using spin columns comprising resins (Example V, columns 5-6). Chu et al teach compositions comprising aqueous solutions of octylthiogluconate used for lysing cells in the protein extraction process (columns 1-2) and Chu et al teach that the octylthiogluconates of the invention can release the protein of interest from the cell membrane or cell wall (column 2). Chu et al also teach that octylthiogluconates have been used for membrane solubilization (column 2). Therefore, claim limitations such as "wherein the cell altering compound inhibits phospholipid sensitive Ca^{+2} dependent protein kinase and attacks cell

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membranes" and "cell membrane compounds alters membrane permeability or disrupts membranes" are taught in the prior art reference.

Chu et al do not teach cationic surfactants comprising ethoxylated amine such as Tomah E -18-15 or Tomah E-18-5.

Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 are used to stabilize protein compositions (see the Abstract). Shultz et al teach that the cationic surfactants of the invention have a hydrophile-lipophile (HLB) index number of about 10 to 17, preferably about 11 to 16 (column 2). Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes (column 8). Shultz et al teach that the cationic surfactants can be added at concentrations ranging from 0.001% up to 1.0% (column 11). In re Venezia 189 USPQ 49 (CCPA 1976) discloses kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Thus, the term "kit" constitutes an "intended use". Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963).

It would be *prima facie* obvious at the time the invention was made to add Tomah E -18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution (see the Abstract and column 8). It would be expected barring evidence to the contrary that a composition comprising octylthioglucosides (cell-altering membrane), Tomah E -18-15 and/or Tomah E-18-5 (cationic surfactant), lysozyme (defoaming agent) and HEPES (buffer salt) would be effective in lysing cells to release proteins and stabilizing the proteins in reaction or storage buffers.

Applicant's Arguments

A) Applicant urges when claimed subject matter had been rejected as obvious in view of a combination of prior art references a proper analysis under 103 requires (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have

a reasonable expectation of success. Applicant urges that the prior art reference alone or in combination do not teach or suggest the claimed invention. Applicant urges that Chu et al is silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound". Applicant urges that Shultz et al adds nothing that remedies the deficiencies in the teachings of Chu et al.

B) Applicant urges that Shultz et al do not suggest that detergents of any type in the HLB range of about 11-16 and is limited to cationic surfactants. Applicant urges that there is no incentive to select any surfactant in this HLB range in order to provide the composition or method of the present invention as presently claimed.

C) Applicant urges that Triton W-30 is listed as a surfactant that does not stabilize the enzyme activity and this anionic surfactant was demonstrated to operate the present invention.

D) Applicant urges that selection of a material such as a surfactant to provide enzyme stability does not automatically presume that it will also provide effective lysis. Applicant urges that some surfactants can form micelles that act to provide additional stabilization of the cellular membrane proteins and makes extraction more difficult. Applicant that one of ordinary skill in the art would not be motivated to combine the teachings of Chu et al and Shultz et al to arrive at the claimed invention with any reasonable expectation of success.

E) Applicant urges that the Examiner has used the instant disclosure as a blueprint. Applicant urges the 103(a) rejection is a hindsight trap in which prior art are strapped together to match whatever is claimed. Applicant urges that this kind of analysis is improper. Applicant urges that Chu et al relates to cell lysis in protein extraction process but provides no teaching or suggestion that additional protein stabilization is desired or necessary. Applicant urges that Chu et al fail to teach a protein stabilization agent so the Examiner finds a reference that does teach a stabilization agent and simply states that if we combine this with Chu et al, Chu et al now teach the combination that is claimed.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed January 25, 2006 have been fully considered but they are not persuasive.

A) In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the claims are directed to a composition comprising at least one surfactant having a lipophilic balance value in the range of about 11 to about 16 and at least one cell

membrane altering compound. Chu et al teach compositions comprising aqueous solutions of octylthioglucoside used for lysing cells in the protein extraction process and further teach that the octylthioglucosides (cell membrane altering compound) of the invention can release the protein of interest from the cell membrane or cell wall. Chu et al do not teach cationic surfactants comprising ethoxylated amine such as Tomah E – 18-15 or Tomah E-18-5 (see the Abstract and column 1). Chu et al teach that other constituents which do no adversely effect the use and benefits of the solution can be added to the invention such as buffers or constituents that influence by the protein that is being expressed (column 2). However, Shultz et al teach that cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 are used to stabilize protein compositions (see the Abstract and columns 1-2). One of ordinary skill in the art would be motivated to add Tomah E –18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al teach that cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution. One ordinary skill in the art would reasonably conclude that the addition cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 would provide a stable aqueous solution.

B) The Examiner disagrees with Applicant's assertions that "Shultz et al is silent with respect to a composition having "at least one surfactant having a hydrophobic-lipophilic balance value in the range from about 11 to about 16" and further in combination with "at least one cell membrane altering compound". Shultz et al teach that cationic surfactants such as Tomah E –18-15 or Tomah E-18-5 are used to stabilize

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protein compositions and further teach that the cationic surfactants of the invention have a hydrophile-lipophile (HLB) index number of about 10 to 17, preferably about 11 to 16 (column 2). It should be noted that no method claims are pending in the present application.

C) To address Applicant's comment regarding "Triton W-30, it should be noted that the prior art teaches several cationic compounds such as Tomah E -18-15 and/or Tomah E-18-5 that can be used to stabilize compositions. Therefore, Triton W-30 is not the only cationic surfactant taught by the prior art references.

D) To address Applicant's comment regarding stability and effective lysis of surfactants, it should be noted that Shultz et al teach that Tomah E -18-15 or Tomah E-18-5 (surfactants) can be used to stabilize proteins and Chu et al teach that octylthioglucosides (cell membrane altering compound) used for lysing cells. Therefore, it should be remembered that it is the combination of all of the cited and relied upon references which make up the state of the art with respect to the claimed invention. Thus, one of ordinary skill in the art would expect success when combining the prior art reference to arrive at the claimed invention.

E) In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). However, it should be remembered that this rejection is an obviousness rejection and not an anticipatory rejection and therefore, Chu et al do not have to teach or disclose all elements of the claims. As stated above, one of ordinary skill in the art would be motivated to combine the prior art references because to add Tomah E -18-15 and/or Tomah E-18-5 to aqueous solutions of Chu et al comprising octylthioglucosides because Shultz et al teach that cationic surfactants such as Tomah E -18-15 or Tomah E-18-5 can be used to stabilize proteins in both storage buffers and reaction enzymes in solution. It should be noted that Chu et al teach that other constituents which do not adversely effect the use and benefits of the solution can be added to the invention such as buffers or constituents that influence by the protein that is being expressed (column 2). Schultz et al provides constituents such as Tomah E -18-15 and/or Tomah E-18-5 which can be used to enhance the stability of aqueous solutions. Thus, there is nothing on the record to show that the combination of teachings would not suggest the claimed invention. Therefore, the rejection is maintained.

Status of Claims

6. Claim 125 is allowed.

Conclusion

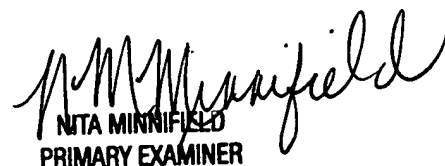
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Vanessa L. Ford
Biotechnology Patent Examiner
July 13, 2006



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